Voltarol® 75 mg SR Tablets

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(diclofenac sodium)

PATIENT INFORMATION LEAFLET

What you need to know about Voltarol Tablets
Your doctor has decided that you need this medicine to help treat your condition.

Please read this leaflet carefully before you start to take your medicine. It contains important information. Keep the leaflet in a safe place because you may want to read it again.
If you have any other questions, or if there is something you don't understand, please ask your doctor or pharmacist.
This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Voltarol 75 mg SR Tablets but it will be referred to as Voltarol Tablets throughout this leaflet. Also available in another strength of 100mg.

In this leaflet:

1. WHAT VOLTAROL TABLETS ARE, AND WHAT THEY ARE USED FOR

Diclofenac sodium, the active ingredient in Voltarol Tablets, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation. Voltarol Tablets and Voltarol Retard Tablets are specially formulated to release the diclofenac sodium slowly.
- Voltarol Tablets relieve pain, reduce swelling and ease inflammation in conditions affecting the joints, muscles and tendons including:
  - Rheumatoid arthritis, osteoarthritis, acute gout, ankylosing spondylitis
  - Backache, sprains and strains, soft tissue sports injuries, frozen shoulder, dislocations and fractures
  - Tendonitis, tenosynovitis, bursitis.
- They are also used to treat pain and inflammation associated with dental and minor surgery.

2. THINGS TO CONSIDER BEFORE YOU START TO TAKE VOLTAROL TABLETS

Some people MUST NOT take Voltarol Tablets. Talk to your doctor if:
- you think you may be allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Voltarol Tablets. (These are listed at the end of the leaflet.) Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, runny nose, skin rash or any other allergic type reaction
- you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces)
- you have had stomach or bowel problems after you have taken other NSAIDs
- you have severe heart, kidney or liver failure
- if you have established heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages
- if you have or have had problems with your blood circulation (peripheral arterial disease) you are more than six months pregnant.
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Voltarol Tablets or other pain medications.

You should also ask yourself these questions before taking Voltarol Tablets:
- Do you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease?
- Do you have kidney or liver problems, or are you elderly?
- Do you have a condition called porphyria?
- Do you suffer from any blood or bleeding disorder? If you do, your doctor may ask you to go for regular check-ups while you are taking these tablets.
- Have you ever had asthma?
- Are you breast-feeding?
- Do you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- Do you have heart problems, or have you had a stroke, or do you think you might be at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol or are a smoker)?
- Do you have diabetes
- Do you smoke
- Do you have Lupus (SLE) or any similar condition?
- Do you have an intolerance to some sugars such as sucrose? (These tablets contain sucrose.)

If the answer to any of these questions is YES, tell your doctor or pharmacist because Voltarol Tablets might not be the right medicine for you.

Are you taking other medicines?
Some medicines can interfere with your treatment. Tell your doctor or pharmacist if you are taking any of the following:
- Medicines to treat diabetes
- Anticoagulants (blood thinning tablets like warfarin)
- Diuretics (water tablets)
- Lithium (used to treat some mental problems)
- Methotrexate (for some inflammatory diseases and some cancers)
- Ciclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants)
- Trimethoprim (a medicine used to prevent or treat urinary tract infections)
- Quinolone antibiotics (for infections)
- Any other NSAID or $COX\text{-}2$ (cyclo-oxgenase-2) inhibitor, for example aspirin or ibuprofen
- Mifepristone (a medicine used to terminate pregnancy)
- Cardiac glycosides (for example digoxin), used to treat heart problems
- Medicines known as SSRIs used to treat depression
- Oral steroids (an anti-inflammatory drug)
- Medicines used to treat heart conditions or high blood pressure, for example betablockers or ACE inhibitors.
- Voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures)
- Colestipol/cholestyramine (used to lower cholesterol)

Always tell your doctor or pharmacist about all the medicines you are taking. *This means medicines you have bought yourself as well as medicines on prescription from your doctor.*

Pregnancy, breast-feeding and fertility
- Are you pregnant or planning to become pregnant? Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. Do not take Voltarol Tablets if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Voltarol Tablets during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Voltarol Tablets can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.
- Are you trying for a baby? Taking Voltarol Tablets may make it more difficult to conceive. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

Will there be any problems with driving or using machinery?
Very occasionally people have reported that Voltarol Tablets have made them feel dizzy, tired or sleepy. Problems with eyesight have also been reported. If you are affected in this way, you should not drive or operate machinery.

Other special warnings
- You should take the lowest dose of Voltarol for the shortest possible time, particularly if you are underweight or elderly.
- There is a small increased risk of heart attack or stroke when you are taking any medicine like Voltarol. The risk is higher if you are taking high doses for a long time. Always follow the doctor's instructions on how much to take and how long to take it for.
- Whilst you are taking these medicines your doctor may want to give you a check-up from time to time.
- If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.
- Because it is an anti-inflammatory medicine, Voltarol Tablets may reduce the symptoms of infection, for example, headache and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking Voltarol Tablets.

3. HOW TO TAKE VOLTAROL TABLETS

The doctor will tell you how many Voltarol Tablets to take and when to take them. Always follow his/her instructions carefully. The dose will be on the pharmacist's label. Check the label carefully. If you are not sure, ask your doctor or pharmacist. Keep taking your tablets for as long as you have been told, unless you have any problems. In that case, check with your doctor.

Take the tablets with or after food.

Swallow the tablets whole with a glass of water.
Do not crush or chew them as this will affect the special 'slow release' system.
The usual doses are:
Adults
100-150 mg daily divided into two or three doses. The number of tablets which you take will depend on the strength the doctor has given you.
Elderly
Your doctor may advise you to take a dose that is lower than the usual adult dose if you are elderly. Your doctor may also want to check closely that the Voltarol Tablets are not affecting your stomach.
These tablets are not suitable for children.

The doctor may also prescribe another drug to protect the stomach to be taken at the same time, particularly if you have had stomach problems before, or if you are elderly, or taking certain other drugs as well.

What if you forget to take a dose?
If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, though, just take the next dose and forget about the one you missed. Do not double up on the next dose to make up for the one missed. Do not take more than 150 mg in 24 hours.

What if you take too many tablets?
If you, or anyone else, accidentally takes too much, tell your doctor or your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken.

4. POSSIBLE SIDE EFFECTS

Voltarol Tablets are suitable for most people, but, like all medicines, they can sometimes cause side effects. Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

<u>Some side effects can be serious</u>
Stop taking Voltarol Tablets and tell your doctor straight away if you notice:
- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick)
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry faeces
- A serious allergic skin reaction which may include large widespread red and/or dark patches, swelling of the skin, blisters, and itching (Generalised bullous fixed drug eruption).
- Wheezing or shortness of breath (bronchospasm)
- Swollen face, lips, hands or fingers
- Yellowing of your skin or the whites of your eyes
- Persistent sore throat or high temperature
- An unexpected change in the amount of urine produced and/or its appearance.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Voltarol Tablets and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain.

If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

<u>The side effects listed below have also been reported.</u>
Common side effects (*These may affect between 1 and 10 in every 100 patients*):
- Stomach pain, heartburn, nausea, vomiting, diarrhoea, indigestion, wind, loss of appetite
- Headache, dizziness, vertigo
- Skin rash or spots
- Raised levels of liver enzymes in the blood.

Rare side effects (*These may affect between 1 in every 1000 to 1 in every 10,000 patients*):
- Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly)
- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Vomiting blood
- Diarrhoea with blood in it or bleeding from the back passage
- Black, tarry faeces or stools
- Drowsiness, tiredness
- Hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness)
- Skin rash and itching
- Fluid retention, symptoms of which include swollen ankles
- Liver function disorders, including hepatitis and jaundice.

Very rare side effects (*These may affect less than 1 in every 10,000 patients*):
Effects on the nervous system:
Tingling or numbness in the fingers, tremor, blurred or double vision, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, mental disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck, disturbances in sensation.

Effects on the stomach and digestive system:
Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, taste changes, lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease).

Effects on the heart, chest or blood:
Palpitations (fast or irregular heart beat), chest pain, hypertension (high blood pressure), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), heart disorders, including congestive heart failure or heart attack, blood disorders (including anaemia).

Effects on the liver or kidneys:
Kidney or severe liver disorders including liver failure, presence of blood or protein in the urine.

Effects on skin or hair:
Serious skin rashes including Stevens-Johnson syndrome, Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight.
Hair loss.

Other side effects that have also been reported include:
Inflammation of the pancreas, impotence. Facial swelling, inflammation of the lining of the brain (meningitis), stroke, throat disorders, confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye.

Not known (*frequency cannot be estimated from the available data*):
- An allergic skin reaction, that may include round or oval patches of redness and swelling of the skin, blistering, and itching (Fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur. Fixed drug eruption usually reoccurs at the same site(s) if the medication is taken again.

Do not be alarmed by this list – most people take Voltarol Tablets without any problems.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE VOLTAROL TABLETS
Do not store above 30°C. Protect from moisture. Protect from heat.

Keep your tablets out of the sight and reach of children.

Do not take Voltarol Tablets after the expiry date which is printed on the outside of the pack.

If your doctor tells you to stop taking the tablets, please take any unused tablets back to your pharmacist to be destroyed. Do not throw them away with your normal household water or waste. This will help to protect the environment.

If your tablets become discoloured or show any other signs of deterioration please contact your doctor or pharmacist before taking this medicine.

6. FURTHER INFORMATION
Voltarol Tablets contain diclofenac sodium.
Each tablet contains 75mg diclofenac sodium as the active ingredient in a sustained release (modified release) formulation.

The tablets also contain the following inactive ingredients: polysorbate 80, sucrose, cetyl alcohol, red iron oxide (E 172), povidone K30, hypromellose, talc, colloidal anhydrous silica, magnesium stearate, titanium dioxide (E 171).

Voltarol Tablets are available as pale pink triangular film-coated tablets, and come in blister packs containing 20 or 30 tablets.

PRODUCT LICENCE HOLDER AND MANUFACTURER
Manufactured by: Novartis Hungaria Kft, Bartok Bela U 43-47, Budapest, 1114, Hungary. Procured from within the EU by Product Licence holder Tenolol Ltd., Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

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